August 7, 1985

VETERINARY SERVICES MEMORANDUM NO. 800.53

Subject: Release of Biological Products

To: Biologics Licensees and Permittees
Director, National Veterinary Services Laboratories
Directors, VS Regions
Biologics Specialists, VS
Area Veterinarians in Charge, VS

I. PURPOSE

The purpose of this memorandum is to establish policy and procedures to comply with Title 9, Code of Federal Regulations, Parts 113 and 116, Sections 113.6 and 116.7, for the release of biological products to licensees.

II. CANCELLATION

Veterinary Services Memorandum No. 800.53, dated June 6, 1984, is rescinded.

III. PROCEDURES

A. Shipment and Receipt of Biologics Samples (VS Form 14-20).

1. Preparation and submission.

Licensees or permittees must complete a form for each shipment of samples. A separate form must be used for each sample type indicated in Block 4.

2. Processing by National Veterinary Services Laboratories (NVSL).

Receipt will be acknowledged by entries in Blocks 23 to 25 and a copy returned to the licensee.

B. Veterinary Biologics Production and Test Report (VS Form 14-8 and 14-8A).

The VS Form 14-8, when signed by a representative of Veterinary Services, is the exclusive disposition document for marketing decisions. If release is not granted or is subject to restrictions, an explanation

is shown. Other documents may be attached for information. If information regarding the status or results of NVSL tests on bulk samples is desired, a preliminary VS Form 14-8 report showing the firm's test results on bulk samples should be submitted. Market release of serials or subserials will require final VS Form 14-8 reports of results of all prescribed tests.

1. Preparation and Submission.

Licensees and permittees must complete a form for each serial or subserial.

For serials prepared for marketing, an original and one copy are to be submitted to the Veterinary Biologics Field Office (VBFO), USDA-APHIS-VS, Pyle Office Park, Suite 103, 515 Grand Avenue, Ames, IA 50010.

For serials involved ln prelicensing evaluation or Outline of Production revision, an original and three copies should be sent to the Senior Staff Veterinarian, Veterinary Biologics Staff (V8S), USDA-APHIS-VS, Room 829, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782.

Complete the VS Form 14-8 as follows:

Block 1 - Enter the earliest date of harvest for any component of a biological product.

Block 2 - Enter the page number. For subsequent pages, use VS Form 14-8A.

Block 3 - Enter the fill date or the date a freeze dried component of a biological product is removed from the freeze dryer.

Block 4 - Enter the license or permit number [9 CFR, Parts 102 or 104, Sections 102.4(c) or 104.7(a)].

Block 5 - Enter the name and mailing address of licensee or permittee.

Block 6 - Compute the expiration date in accordance with the Outline of Production and enter the date [9 CFR, Parts 101 and 114, Sections 101.4(f) and 114.3].

Block 7 - Use the code number from current product license or permit.

Block 8 - Complete, if applicable.

Block 9 - Enter the serial or subserial number [9 CFR, Part 101, Sections 101.3(h) and (i) and 101.4(e)].

Block 10 - Use the true name from the current license or permit [9 CFR Part 101, Section 101.4(d)].

Block 11 - All tests conducted to support release of the serial must be reported, including no tests, inconclusive tests, and retests. (A "No Test" is one in which a conclusion is not possible because of an obvious failure is an essential part of the test. An "Inconclusive Test" is one in which a conclusion of either satisfactory or unsatisfactory cannot be reached based upon the results obtained). If space in Block 11 Is not adequate, use VS Form 14-8A for reporting additional test results.

Block 11B & C - Enter test dates.

Block 11D - Enter all test results. The VBFO may be contacted regarding proper format for reporting specific tests.

Block 11E - Enter the test conclusions. Explain in Block 12E, Remarks, the basis for a "No Test" or "Inconclusive" entry.

Block 12 - Enter the inventory of containers or quantities (finished or completed) to which testing and disposition apply. For serials designated as "Eligible for Release," this should closely approximate the quantity to be marketed. For serials not to be marketed, indicate at least estimated quantity.

Block 12A - Use a separate line for each size container. Counts should be as accurate as possible. If later counts are significantly different, an amended VS Form 14-8 should be submitted with quantity corrected.

Block 12B - Indicate doses, ml, or units.

Block 12C - Enter total quantity where dose size is variable, for products such as antiserums and antitoxins.

Block 12D - Calculate the total number of containers.

Block 12E - Any pertinent remarks may be placed in this block.

Block 13 - Mark the applicable disposition block. "Destroyed" is a certification of actual destruction, not the intent to destroy. If destruction is for other than unsatisfactory tests, the reason should be shown. Note that rebottling and reprocessing must be approved. "Other" is used for reports of corrected inventory counts, supplemental information, etc.

Block 14 - One copy must have the original signature of a person whose authorization has been previously filed with USDA [9 CFR 114.7(a)].

Block-15 - Self-explanatory.

Block 16 - Enter date of signature.

2. Preparation of VS Form 14-8A.

All instructions given for Form 14-8 apply to Form 14-8A.

3. Processing by Veterinary Services.

The VS Form 14-8 will be reviewed for compliance with requirements. When exceptions are noted, the licensee or permittee will be notified of needed corrections or additions.

a. Market Serials Not Selected for Testing.

Release will be granted or withheld by completion of Blocks 17 through 20.

b. Market Serials Selected for Testing.

NVSL, within 14 calendar days after receipt of test samples, will select serials and initiate tests. Exceptions to the initiation of tests within 14 days may be made due to special circumstances. Licensees will be notified in writing whenever such exceptions are made.

NVSL will notify the VBFO that the serial has been selected and provide the approximate test completion date.

On completion of all tests, release will be granted or withheld by completion of Blocks 17 through 20.

c. Serials for Prelicensing or Outline of Production Revision or Evaluation.

After review, VBS will transmit the original and one copy to the VBFO and one copy to NVSL. Except for the 14-day limit on initiation of tests, procedures will then be the same as for market serials.

d. Expediting Market Serial Release.

NVSL will transmit a report indicating the activity for each licensee which will constitute an official record of NVSL actions and recommendations.

On receipt of a VS Form 14-8 indicating that a serial is eligible for release and if long-term tests at NVSL are not complete, the firm will be informed using a postcard or a collect phone call (if requested by the licensee).

When notified that a serial is either not to be tested or that NVSL tests are completed, Blocks 17-20 will be completed.

e. Distribution.

Veterinary Services will retain the completed original VS Form 14-8. One completed copy with related documents will be sent to the licensee or the permittee.

C. Veterinary Services Laboratory Test Reports.

1. Preparation and Processing.

a. Serials for Marketing.

NVSL will report test results on each serial or subserial with supplementary reports, if indicated.

b. Serials Involved in Prelicensing Evaluation or Outline of Production Revisions.

NVSL will report test results to VBS with supplementary reports, if indicated. VBS will make recommendations to VBFO on disposition.

2. Distribution.

The completed test report will be sent by VBFO to the licensee or permittee. Veterinary Services will retain copies, as appropriate.

/s/

J. K. Atwell
Deputy Administrator
Veterinary Services